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Contents



[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

[1] Text with EEA relevance

[1] Text with EEA relevance

II

*(Non-legislative acts)*

# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2015/683

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize MON 87460 (MON 8746Ø-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2749)*

**(Only the French and Dutch texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 29 May 2009, Monsanto Europe SA submitted to the competent authority of The Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MON 87460 maize ('the application').

(2) The application also covers the placing on the market of MON 87460 maize in products consisting of it or containing it for any other uses than food and feed as any other maize, with the exception of cultivation.

(3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 15 November 2012, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that MON 87460 maize, as described in the application, is as safe as its conventional counterpart and non-GM reference varieties with respect to potential effects on human and animal health and the environment, in the context of its intended use. EFSA performed a specific risk assessment linked to the presence of the antibiotic resistance marker *nptII gene* in MON 87460. The detailed analysis of risks associated with a theoretically possible horizontal gene transfer did not raise safety concerns to human or animal health or to the environment in the context of MON 87460 intended uses. In its

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

opinion, EFSA also considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of that Regulation.

(5) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(6) Taking into account those considerations, authorisation should be granted for the products containing, consisting, or produced from MON 87460 maize, as described in the application, called ('the products').

(7) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(8) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from MON 87460 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO with the exception of food products for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(9) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]), lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(10) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(11) All relevant information on the authorisation of the products should be entered in the EU register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([4]).

(13) The applicant has been consulted on the measures provided for in this Decision.

(14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([2]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([3]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([4]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified maize (*Zea mays* L.) MON 87460, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON 8746Ø-4, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON 8746Ø-4 maize;

(b) feed containing, consisting of, or produced from MON 8746Ø-4 maize;

(c) MON 8746Ø-4 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON 8746Ø-4 maize with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**EU register**

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe SA, Belgium, representing Monsanto Company, United States of America.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Monsanto Europe SA, Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder**

Name: Monsanto Europe SA

Address: Avenue de Tervuren 270-272, 1150 Brussels, Belgium

On behalf of *Monsanto Company,800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America*.

(b) **Designation and specification of the products**

1. foods and food ingredients containing, consisting of, or produced from MON 8746Ø-4 maize;
2. feed containing, consisting of, or produced from MON 8746Ø-4 maize;
3. MON 8746Ø-4 maize in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified MON 8746Ø-4 maize, as described in the application, expresses the cold shock protein B (CspB) which aims to reduce yield loss caused by drought stress. An *nptII* gene, conferring kanamycine and neomycine resistance, was used as a selective marker in the genetic modification process.

(c) **Labelling**

1. For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON 8746Ø-4 maize with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— Event-specific real-time PCR based method for the quantification of MON 8746Ø-4 maize.

— Validated on genomic DNA, extracted from seeds, by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

— Reference Material: AOCS 0709-A and AOCS 0406-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON 8746Ø-4

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House (to be entered in the EU register of genetically modified food and feed when notified).

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC [to be entered in the EU register of genetically modified food and feed when notified).

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/684

## of 24 April 2015

## authorising the placing on the market of genetically modified maize NK603 (MON-ØØ6Ø3-6) and renewing the existing maize NK603 (MON-ØØ6Ø3-6) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2753)*

**(Only the Dutch and the French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 7(3), 11(3), 19(3) and 23(3) thereof,

Whereas:

(1) By Commission Decision 2004/643/EC ([2]), the placing on the market of feed containing or consisting of NK603 maize and NK603 maize in products consisting of it or containing it for any other uses than food and feed, with the exception of cultivation, is authorised in accordance with Directive 2001/18/EC of the European Parliament and of the Council ([3]), until 17 October 2014.

(2) By Commission Decision 2005/448/EC ([4]), the placing on the market of foods and food ingredients containing, consisting of or produced from NK603 maize is authorised in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council ([5]), until 2 March 2015.

(3) Food and feed additives and feed materials produced from genetically modified maize NK603 were placed on the market before the entry into force of Regulation (EC) No 1829/2003 and were notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation when it came into force.

(4) On 2 August 2005, Monsanto Europe S.A. submitted to the European Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of food and feed additives and feed materials produced from NK603 maize which were previously notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation.

(5) On 2 August 2005, Monsanto Europe S.A. submitted to the competent authority of the Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from NK603 maize.

(6) This application also covered the placing on the market of NK603 maize in products consisting of it or containing it for any other uses than food and feed as any other maize, including the seeds for cultivation.

(7) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Commission Decision 2004/643/EC of 19 July 2004 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L. line NK603) genetically modified for glyphosate tolerance (OJ L 295, 18.9.2004, p. 35).

([3]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

([4]) Commission Decision 2005/448/EC of 3 March 2005 authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 158, 21.6.2005, p. 20).

([5]) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

(8) On 25 March 2008, the Spanish Competent Authority and its Biosafety Commission provided to the European Food Safety Authority ('EFSA') its opinion on the environmental risk assessment in line with Articles 6(3)(c) and 18(3)(c) of Regulation (EC) No 1829/2003 and it concluded that according to the current state of scientific knowledge and after examining the existing information and data provided by the applicant, the Spanish Commission on Biosafety could give a favourable opinion to the commercialisation in the EU of maize NK603 if the proposals and conditions established in the Environmental Risk Assessment report are implemented.

(9) On 11 June 2009, EFSA gave a favourable opinion for both applications in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that NK603 maize, as described in the application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment ([1]). In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of that Regulation.

(10) In its opinion, EFSA also concluded that the environmental monitoring plan submitted by the applicant is in line with the intended uses of the products.

(11) On 14 March 2014, Monsanto Europe S.A. informed the European Commission of its decision to amend the scope of the abovementioned new application to no longer include authorisation for cultivation of NK603 maize in the European Union.

(12) Taking into account those considerations, authorisation should be granted for the products, with the exception of cultivation, and the environmental monitoring plan should be adapted to the modified scope.

(13) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([2]).

(14) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from NK603 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO with the exception of food products for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(15) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([3]), lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(16) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([4]). The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(17) All relevant information on the authorisation of the products should be entered in the EU register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

([1]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00626

([2]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([3]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([4]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

(18) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([1]).

(19) Commission Decisions 2004/643/EC and 2005/448/EC should be repealed.

(20) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified maize (*Zea mays* L.) NK603, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ6Ø3-6, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-ØØ6Ø3-6 maize;

(b) feed containing, consisting of, or produced from MON-ØØ6Ø3-6 maize;

(c) MON-ØØ6Ø3-6 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label and in the documents accompanying the products containing or consisting of MON-ØØ6Ø3-6 maize with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

([1]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 5*

**EU register**

The information set out in the Annex to this Decision shall be entered in the EU register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Repeal**

Decisions 2004/643/EC and 2005/448/EC are repealed.

*Article 9*

**Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels — Belgium

On behalf of *Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States of America*.

(b) **Designation and specification of the products**

1. Foods and food ingredients containing, consisting of, or produced from MON-ØØ6Ø3-6 maize.
2. Feed containing, consisting of, or produced from MON-ØØ6Ø3-6 maize.
3. MON-ØØ6Ø3-6 maize in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified MON-ØØ6Ø3-6 maize, as described in the applications, expresses the CP4 EPSPS protein which confers tolerance to the glyphosate herbicides.

(c) **Labelling**

1. For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-ØØ6Ø3-6 maize with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— Event specific real-time PCR based method for the quantification of MON-ØØ6Ø3-6 maize.

— Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, on genomic DNA extracted from Certified Reference Material, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm

— Reference Material: ERM®-BF415 accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at https://irmm.jrc.ec.europa.eu/rmcatalogue

(e) **Unique identifier**

MON-ØØ6Ø3-6

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House [to be entered in the EU register of genetically modified food and feed when notified].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC [to be entered in the EU register of genetically modified food and feed when notified].

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/685

## of 24 April 2015

## authorising the placing on the market of genetically modified cotton MON 15985 (MON-15985-7) and renewing the authorisation for existing genetically modified cotton MON 15985 (MON-15985-7) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2755)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 7(3), 11(3), 19(3) and 23(3) thereof,

Whereas:

(1) On 9 December 2004, Monsanto Europe S.A. submitted to the competent authority of the United Kingdom an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 for the placing on the market of food and feed produced from genetically modified cotton MON 15985.

(2) Food additives, feed materials and feed additives produced from genetically modified cotton MON 15985 were placed on the market before the entry into force of Regulation (EC) No 1829/2003 and were notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation.

(3) On 17 April 2007, Monsanto Europe S.A. submitted to the Commission an application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 for the renewal of the authorisation for existing food additives, feed materials and feed additives produced from genetically modified cotton MON 15985.

(4) On 22 April 2008, Monsanto Europe S.A. submitted a new broader application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from genetically modified cotton MON 15985, including the existing products ('the application') and on 2 July 2008 withdrew its application submitted on 9 December 2004.

(5) The application also covers the placing on the market of genetically modified cotton MON 15985 in products consisting of it or containing it for other uses than food and feed as any other cotton, with the exception of cultivation.

(6) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003 the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to that Directive. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(7) On 29 July 2014, the European Food Safety Authority ('EFSA') gave an opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). It concluded that genetically modified cotton MON 15985, as described in the application, is as safe as its conventional counterpart and non-genetically modified cotton commercial varieties and is unlikely to have adverse effects on human and animal health and the environment, notwithstanding the incompleteness in the agronomic and phenotypic dataset. Considering the scope of these

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on applications (EFSA-GMO-UK-2008-57 and EFSA-GMO-RX-MON15985) for the placing on the market of insect-resistant genetically modified cotton MON 15985 for food and feed uses, import and processing, and for renewal of authorisation of existing products produced from cotton MON 15985, both under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2014;12(7):3770, 42 pp. doi:10.2903/j.efsa.2014.3770

applications and the poor ability of cotton to survive outside cultivated fields, EFSA concluded that the likelihood of any adverse environmental impacts due to the accidental release into the environment of viable seeds from cotton MON 15985 is very low.

(8) EFSA concluded that the analysis of horizontal gene transfer from genetically modified cotton MON 15985 to bacteria did not indicate a risk to human or animal health or to the environment in the context of its intended uses, considering the expected low frequency of gene transfer from plant to bacteria compared with that between bacteria, and the very low exposure to DNA from genetically modified cotton MON 15985.

(9) EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(10) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(11) Consequently, authorisation should be granted to the products containing, consisting of, or produced from genetically modified cotton MON 15985.

(12) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(13) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from genetically modified cotton MON 15985. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing, consisting of, or produced from MON 15985 cotton, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.

(14) Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]) lays down labelling requirements for products containing or consisting of GMOs. Traceability requirements for those products are laid down in paragraphs 1 to 5 of Article 4 and traceability requirements for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(15) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

(16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(17) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([4]).

(18) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([2]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([3]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([4]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.) MON 15985, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-15985-7, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-15985-7 cotton;

(b) feed containing, consisting of, or produced from MON-15985-7 cotton;

(c) MON-15985-7 cotton in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-15985-7 cotton, with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels — Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States of America.

(b) **Designation and specification of the products**

1. Foods and food ingredients containing, consisting of, or produced from MON-15985-7 cotton.
2. Feed containing, consisting of, or produced from MON-15985-7 cotton.
3. MON-15985-7 cotton in products containing it or consisting of it for any other use than those provided in points 1 and 2, with the exception of cultivation.

The genetically modified MON-15985-7 cotton, as described in the application, expresses the Cry2Ab2 and Cry1Ac proteins which confer protection against certain lepidopteran pests and GUS protein which acts as selection marker. In addition, an *npt*II gene, conferring kanamycin and neomycin resistance, and *aad*A gene, conferring spectinomycin and streptomycin resistance, were used as selective markers in the genetic modification process.

(c) **Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-15985-7 cotton with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

1. Event specific real-time PCR based method for the quantification of MON-15985-7.
2. Validated on genomic DNA, extracted from seeds by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx
3. Reference Material: AOCS 0804-D and AOCS 0804-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON-15985-7

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan for environmental effects**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/686

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87769 (MON-87769-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2757)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 14 September 2009, Monsanto Europe SA submitted to the competent authority of the United Kingdom an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MON 87769 soybean ('the application').

(2) The application also covers the placing on the market of MON 87769 soybean in products consisting of it or containing it for any other uses than food and feed as any other soybean, with the exception of cultivation.

(3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 16 May 2014, the European Food Safety Authority ('EFSA') gave a favourable opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that MON 87769 soybean, as described in the application, is as safe as its conventional counterpart and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of the application.

(5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(6) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(7) In addition, EFSA recommended a post-market monitoring plan to be implemented, focusing on the collection of consumption data for the European population.

(8) Taking into account those considerations, authorisation should be granted to the products.

(9) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([4]).

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on application EFSA-GMO-UK-2009-76 for the placing on the market of soybean MON87769 genetically modified to contain stearidonic acid, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2014; 12(5):3644, 41 pp. doi:10.2903/j.efsa.2014.3644.
([4]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

(10) Food, food ingredients and feed containing, consisting of, or produced from soybean MON 87769 should be labelled in accordance with the requirements provided for in Article 13(1) and Article 25(2)(a) and (b) of Regulation (EC) No 1829/2003.

(11) On the basis of the EFSA opinion, confirming that fatty acid composition of the seeds of MON 87769 soybean and derived oil has been changed in relation to the conventional counterpart, specific labelling appears to be necessary in accordance with Articles 13(2)(a) and 25(2)(c). This specific labelling should ensure informed choice without misleading the consumers.

(12) In order to ensure the use of the products containing or consisting of MON 87769 soybean within the limits of the authorisation provided for by this Decision, the labelling of these products, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(13) Regulation (EC) No 1830/2003 of the European Parliament and of the Council [1] lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(14) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC [2]. The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(15) The authorisation holder should also submit annual reports on the implementation and the results of the activities set out in the post-market monitoring plan.

(16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(17) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council [3].

(18) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified soybean (*Glycine max* (L.) Merr.) MON 87769, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-87769-7, as provided for in Regulation (EC) No 65/2004.

[1] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[2] Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

[3] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-87769-7 soybean;

(b) feed containing, consisting of, or produced from MON-87769-7 soybean;

(c) MON-87769-7 soybean in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with stearidonic acid' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.

3. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-87769-7 soybean with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003**

1. The authorisation holder shall ensure that the post-market monitoring plan of the MON-87769-7 soybean oil, as set out in point (g) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the post-market monitoring plan for the duration of the authorisation.

*Article 6*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe SA, Belgium, representing Monsanto Company, United States.

*Article 8*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9*

**Addressee**

This Decision is addressed to Monsanto Europe SA, Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder:**

Name: Monsanto Europe SA

Address: Avenue de Tervuren 270-272, 1150 Brussels, Belgium

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States.

(b) **Designation and specification of the products:**

1. foods and food ingredients containing, consisting of, or produced from MON-87769-7 soybean;

2. feed containing, consisting of, or produced from MON-87769-7 soybean;

3. MON-87769-7 soybean in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified MON-87769-7 soybean, as described in the application, expresses Δ15 desaturase which results in conversion of linoleic acid to α-linolenic acid and Δ6 desaturase which results in conversion of α-linolenic acid to stearidonic acid (SDA). SDA is a normal intermediate in the formation of the long-chain omega-3 polyunsaturated fatty acids.

(c) **Labelling:**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with stearidonic acid' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.

3. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-87769-7 soybean with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

1. Event-specific real-time PCR based method for the quantification of MON-87769-7 soybean.

2. Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from soybean seeds, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

3. Reference Material: AOCS 0809-B and AOCS 0906-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier:**

MON-87769-7

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Biosafety Clearing-House, Record ID: see (*to be completed when notified*).

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

*Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003*

1. The authorisation holder shall collect the following information:

   (i) quantities of MON-87769-7 soybean oil and MON-87769-7 soybeans for oil extraction, imported into the European Union for the placing on the market as or in products for food;

   (ii) in case of import of products referred to in point (i), results of searches in the FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed;

   (iii) in case of import of products referred to in point (i), data on the different categories of food and feed uses of MON-87769-7 oil in the EU.

2. The authorisation holder shall, based on the information collected and reported, review the nutritional assessment conducted as part of the risk assessment.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(Link: *plan published on the internet*)

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/687

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rape MON 88302 (MON-883Ø2-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2759)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 31 August 2011, Monsanto Europe S.A. submitted to the competent authority of Belgium an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MON 88302 oilseed rape ('the application').

(2) The application also covers the placing on the market of MON 88302 oilseed rape in products consisting of it or containing it for any other uses than food and feed as any other oilseed rape, with the exception of cultivation.

(3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 17 June 2014, the European Food Safety Authority ('EFSA') gave a favourable opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that MON 88302 oilseed rape is as safe as its conventional counterpart and non-GM oilseed rape commercial varieties and is unlikely to have adverse effects on human and animal health and the environment in the context of the scope of the application.

(5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(6) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(7) Taking into account those considerations, authorisation should be granted to the products.

(8) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([4]).

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on application EFSA-GMO-BE-2011-101 for the placing on the market of herbicide-tolerant genetically modified oilseed rape MON 88302 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2014; 2(6):3701, 37 pp. doi:10.2903/j.efsa.2014.3701.
([4]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

(9) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from MON 88302 oilseed rape. However, in order to ensure the use of the products containing or consisting of MON 88302 oilseed rape within the limits of the authorisation provided for by this Decision, the labelling of these products, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(10) Regulation (EC) No 1830/2003 of the European Parliament and of the Council [1] lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(11) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC [2]. The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or of specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(12) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council [3].

(14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified oilseed rape (*Brassica napus* L.) MON 88302, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-883Ø2-9, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-883Ø2-9 oilseed rape;

[1] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[2] Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

[3] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

(b) feed containing, consisting of, or produced from MON-883Ø2-9 oilseed rape;

(c) MON-883Ø2-9 oilseed rape in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'oilseed rape'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-883Ø2-9 oilseed rape with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, B-1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holder:**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, B-1150 Brussels — Belgium

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167 — United States.

(b) **Designation and specification of the products:**

1. foods and food ingredients containing, consisting of, or produced from MON-883Ø2-9 oilseed rape;
2. feed containing, consisting of, or produced from MON-883Ø2-9 oilseed rape;
3. MON-883Ø2-9 oilseed rape in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified MON-883Ø2-9 oilseed rape, as described in the application, expresses the CP4 5-enolpyruvyl-shikimate-3-phosphate synthase (CP4 EPSPS) protein which confers tolerance to glyphosate-based herbicides.

(c) **Labelling:**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'oilseed rape';
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-883Ø2-9 oilseed rape with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

1. Event specific real-time PCR based method for the quantification of MON-883Ø2-9 oilseed rape;
2. Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from oilseed rape seeds, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx;
3. Reference Material: AOCS 1011-A and AOCS 0304-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm.

(e) **Unique identifier:**

MON-883Ø2-9

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/688

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton MON 88913 (MON-88913-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2760)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 28 February 2007, Monsanto Europe S.A. submitted to the competent authority of the United Kingdom an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MON 88913 cotton ('the application').

(2) The application also covers the placing on the market of MON 88913 cotton in products consisting of it or containing it for other uses than food and feed as any other cotton, with the exception of cultivation.

(3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 29 July 2013, the European Food Safety Authority ('EFSA') gave an opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It could not reach an overall conclusion on the MON 88913 cotton due to the use by the applicant of an outdated toxin database for the bioinformatic analyses.

(5) On 18 October 2013, the applicant provided new bioinformatic analyses using updated databases.

(6) On 13 March 2014, EFSA published a statement complementing its scientific opinion ([4]), taking into account those updated bioinformatic analyses, and concluded that MON 88913 cotton assessed in the initial scientific opinion and in the supplementary bioinformatic dataset is as safe and nutritious as its conventional counterpart and commercial cotton varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses.

(7) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on application EFSA-GMO-UK-2007-41 for the placing on the market of herbicide-tolerant genetically modified cotton MON 88913 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2013;11(7):3311, 25 pp. doi:10.2903/j.efsa.2013.3311.

([4]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Statement complementing the EFSA opinion on application EFSA-GMO-UK-2007-41 (cotton MON 88913 for food and feed uses, import and processing) taking into consideration updated bioinformatic analyses. *EFSA Journal* 2014;12(3):3591, 6 pp. doi:10.2903/j.efsa.2014.3591.

(8) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(9) Taking into account those considerations, authorisation should be granted to the products.

(10) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(11) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from MON 88913 cotton. However, in order to ensure the use of the products containing or consisting of MON 88913 cotton within the limits of the authorisation provided for by this Decision, the labelling of these products, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(12) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]) lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(13) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or of specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

(14) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(15) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([4]).

(16) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.) MON 88913, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-88913-8, as provided for in Regulation (EC) No 65/2004.

([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([2]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([3]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([4]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-88913-8 cotton;

(b) feed containing, consisting of, or produced from MON-88913-8 cotton;

(c) MON-88913-8 cotton in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.

2. The words 'not for cultivation' shall appear on the label and in the documents accompanying the products containing or consisting of MON-88913-8 cotton with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holder:**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels — Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States.

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of, or produced from MON-88913-8 cotton;

(2) feed containing, consisting of, or produced from MON-88913-8 cotton;

(3) MON-88913-8 cotton in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified MON-88913-8 cotton, as described in the application, expresses the CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) which confers tolerance to glyphosate-based herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton';

(2) The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-88913-8 cotton with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

(1) Event specific real-time PCR based method for the quantification of MON-88913-8 cotton;

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from cotton leaves, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

(3) Reference Material: AOCS 0906-D and AOCS 0804-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier:**

MON-88913-8

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

*Note:* Links to relevant documents may need to be modified over time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/689

## of 24 April 2015

## renewing the authorisation for existing genetically modified cotton MON 531 (MON-ØØ531-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2761)*

**(Only the French and Dutch texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 11(3) and 23(3) thereof,

Whereas:

(1) Food additives, feed materials and feed additives produced from genetically modified cotton MON 531 were placed on the market before the entry into force of Regulation (EC) No 1829/2003 and were notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation.

(2) On 17 April 2007, Monsanto Europe S.A. submitted to the Commission an application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 for the renewal of the authorisation for existing food additives, feed materials and feed additives produced from genetically modified cotton MON 531 ('the application').

(3) On 16 June 2011, Monsanto Europe S.A. requested an extension of the scope of the application to include food cottonseed oil produced from genetically modified cotton MON 531, which was previously notified as an existing product in accordance with Article 8(1)(a) of Regulation (EC) No 1829/2003.

(4) The scope of the application as extended covers the full range of current commercial uses of food and feed produced from cotton as defined in Articles 3(1)(c) and 15(1)(c) of Regulation (EC) No 1829/2003.

(5) On 16 September 2011, the European Food Safety Authority ('EFSA') gave a favourable opinion ([2]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that products derived from genetically modified cotton MON 531, as described in the application, are as safe as products derived from its conventional counterpart, in the context of their intended uses.

(6) EFSA concluded that the analysis of horizontal gene transfer from genetically modified cotton MON 531 to bacteria did not indicate a risk to human or animal health or to the environment in the context of its intended uses, considering the expected low frequency of gene transfer from plant to bacteria compared with that between bacteria, and the very low exposure to DNA from genetically modified cotton MON 531.

(7) EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(8) Consequently, authorisation should be renewed for the products produced from genetically modified cotton MON 531.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on application EFSA-GMO-RX-MON531 for renewal of the authorisation for continued marketing of existing cottonseed oil, food additives, feed materials and feed additives produced from MON 531 cotton that were notified under Articles 8(1)(a), 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2011;9(9):2373. [1-30] doi:10.2903/j.efsa.2011.2373.

(9) A unique identifier should be assigned to each genetically modified organism as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(10) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed produced from genetically modified cotton MON 531.

(11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([2]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.) MON 531, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ531-6, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Renewal of authorisation**

The authorisation for the placing on the market of the following products is renewed for the purposes of Articles 11 and 23 of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) food produced from MON-ØØ531-6 cotton;

(b) feed produced from MON-ØØ531-6 cotton.

*Article 3*

**Labelling**

For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'cotton'.

*Article 4*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([2]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 5*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

*Article 6*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 7*

**Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, 1150 Brussels — Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States of America.

(b) **Designation and specification of the products**

1. Food produced from MON-ØØ531-6 cotton.
2. Feed produced from MON-ØØ531-6 cotton.

The genetically modified MON-ØØ531-6 cotton, as described in the application, expresses the Cry1Ac protein which confers resistance to lepidopteran pests. An *npt*II gene, conferring kanamycin and neomycin resistance, and *aad*A gene, conferring spectinomycin and streptomycin resistance, were used as selective markers in the genetic modification process.

(c) **Labelling**

For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'cotton'.

(d) **Method for detection**

1. Event specific real-time PCR based method for the quantification of MON-ØØ531-6 cotton.
2. Validated on genomic DNA, extracted from seeds, by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm
3. Reference Material: AOCS 0804-C and AOCS 0804-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON-ØØ531-6

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Not applicable.

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan for environmental effects**

Not required.

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/690

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614xLLCotton25 (BCS-GHØØ2-5xACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2762)*

**(Only the German text is authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 1 February 2010, Bayer CropScience AG submitted to the competent authority of The Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from GHB614xLLCotton25 cotton ('the application').

(2) The application also covers the placing on the market of GHB614xLLCotton25 cotton in products consisting of it or containing it for any other uses than food and feed as any other cotton, with the exception of cultivation.

(3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 16 May 2014, the European Food Safety Authority ('EFSA') gave a favourable opinion ([3]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that GHB614xLLCotton25 cotton, as described in the application, is as safe as its conventional counterpart and commercial cotton varieties and that it is unlikely to have any adverse effects on human and animal health or the environment, in the context of its intended uses.

(5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(6) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(7) Taking into account those considerations, authorisation should be granted to the products.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on application EFSA-GMO-NL-2010-77 for the placing on the market of herbicide-tolerant genetically modified cotton GHB614×LLCotton25 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience. EFSA Journal 2014;12(5):3680, 41 pp. doi:10.2903/j.efsa.2014.3680.

(8) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(9) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from GHB614xLLCotton25 cotton. However, in order to ensure the use of the products containing or consisting of GHB614xLLCotton25 cotton within the limits of the authorisation provided for by this Decision, the labelling of these products, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(10) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]) lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(11) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or of specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.

(12) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([4]).

(14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.) GHB614xLLCotton25, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ2-5xACS-GHØØ1-3, as provided for in Regulation (EC) No 65/2004.

([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([2]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([3]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([4]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from BCS-GHØØ2-5xACS-GHØØ1-3 cotton;

(b) feed containing, consisting of, or produced from BCS-GHØØ2-5xACS-GHØØ1-3 cotton;

(c) BCS-GHØØ2-5xACS-GHØØ1-3 cotton in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of BCS-GHØØ2-5xACS-GHØØ1-3 cotton with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Bayer CropScience AG.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Bayer CropScience AG, Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein, Germany.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holder:**

Name: Bayer CropScience AG

Address: Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein — Germany

(b) **Designation and specification of the products:**

1. foods and food ingredients containing, consisting of, or produced from BCS-GHØØ2-5xACS-GHØØ1-3 cotton;
2. feed containing, consisting of, or produced from BCS-GHØØ2-5xACS-GHØØ1-3 cotton;
3. BCS-GHØØ2-5xACS-GHØØ1-3 cotton in products containing it or consisting of it for any other than 1 and 2, with the exception of cultivation.

The genetically modified BCS-GHØØ2-5xACS-GHØØ1-3 cotton, as described in the application, expresses the phosphinothricin acetyl transferase (PAT) protein which confers tolerance to glufosinate-ammonium herbicides and the modified 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS) protein which confers tolerance to glyphosate herbicides.

(c) **Labelling:**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton';
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of BCS-GHØØ2-5xACS-GHØØ1-3 cotton with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

1. Event specific real-time PCR based method for the quantification of BCS-GHØØ2-5xACS-GHØØ1-3 cotton;
2. Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from cotton leaves, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx;
3. Reference Material: AOCS 1108-A, AOCS 0306-A and AOCS 0306-E are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm.

(e) **Unique identifier:**

BCS-GHØØ2-5xACS-GHØØ1-3

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post- market monitoring requirements for the use of the food for human consumption:**

Not required.

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/691

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean BPS-CV127-9 (BPS-CV127-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2764)*

**(Only the German text is authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 5 January 2009, BASF Plant Science GmbH submitted to the competent authority of The Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from BPS-CV127-9 soybean ('the application').

(2) The application also covers the placing on the market of soybean BPS-CV127-9 in products consisting of it or containing it for any other uses than food and feed as any other soybean, with the exception of cultivation.

(3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 17 January 2014, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that BPS-CV127-9 soybean, as described in the application, is as safe as its conventional counterpart and commercial soybean varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses ([3]). However, the EFSA GMO Panel could not conclude on the use of forage as or in feed as data on compositional analysis of forage were not in line with the EFSA requirements and no new data on forage were provided by the applicant.

(5) Since forage is usually used where the cultivation takes place and no import is therefore expected in the EU, forage could be excluded from the scope of this authorisation.

(6) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(7) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

([3]) EFSA Panel on Genetically Modified Organisms (GMO), 2014. Scientific Opinion on application (EFSAGMO-NL-2009-64) for the placing on the market of herbicide-tolerant genetically modified soybean BPS-CV127-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from BASF Plant Science. *EFSA Journal* 2014; 12(1):3505, 30 pp. doi: 10.2903/j.efsa.2014.3505.

(8) Taking into account those considerations, authorisation should be granted to the products, with the exception of forage as or in feed.

(9) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(10) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from BPS-CV127-9 soybean. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO for which authorisation is requested, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(11) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]) lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(12) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(13) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(14) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and point (c) of Article 15(2) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([4]).

(15) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified soybean (*Glycine max* (L.) Merr.) BPS-CV127-9, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BPS-CV127-9, as provided for in Regulation (EC) No 65/2004.

([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([2]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([3]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([4]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from BPS-CV127-9 soybean;

(b) feed containing, consisting of, or produced from BPS-CV127-9 soybean with the exception of forage;

(c) BPS-CV127-9 soybean, in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of BPS-CV127-9 soybean with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be BASF Plant Science GmbH, Germany.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to BASF Plant Science GmbH, Carl-Bosch-Str. 38, 67056 Ludwigshafen, Germany.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder:**

Name: BASF Plant Science GmbH

Address: Carl-Bosch-Str.38, 67056 Ludwigshafen, Germany

(b) **Designation and specification of the products:**

1. foods and food ingredients containing, consisting of, or produced from BPS-CV127-9 soybean;
2. feed containing, consisting of, or produced from BPS-CV127-9 soybean with the exception of forage;
3. BPS-CV127-9 soybean, in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified BPS-CV127-9 soybean, as described in the application, expresses a mutant acetohydroxyacid synthase large sub-unit of *Arabidopsis thaliana* (AtAHAS) which confers tolerance to the imidazolinone herbicides.

(c) **Labelling:**

1. For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of BPS-CV127-9 soybean with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

— Event-specific real-time PCR based method for the quantification of BPS-CV127-9 soybean.

— Validated on seeds by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

— Reference Material: AOCS 0911-B and AOCS 0911-D are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier:**

BPS-CV127-9

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Biosafety Clearing-House, Record ID: see (*to be completed when notified*).

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(Link: *plan published on the internet*)

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/692

## of 24 April 2015

## concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a carnation (*Dianthus caryophyllus* L., line 25958) genetically modified for flower colour

*(notified under document C(2015) 2765)*

**(Only the Dutch text is authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ([1]), and in particular the first subparagraph of Article 18(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority of the Member State that received the notification for the placing on the market of that product, in accordance with the procedure laid down in that Directive.

(2) A notification concerning the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line 25958) was submitted by Florigene Ltd, Melbourne, Australia, to the competent authority of the Netherlands in March 2009.

(3) The notification covers import, distribution and retailing of cut flowers of carnation *Dianthus caryophyllus* L., line 25958 as for any other carnation.

(4) In accordance with the procedure established by Article 14 of Directive 2001/18/EC, the competent authority of the Netherlands prepared an assessment report, which concluded that no reasons have emerged on the basis of which consent for the placing on the market of cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line 25958) for ornamental use should be withheld, if specific conditions are fulfilled.

(5) In its assessment report, the competent authority of the Netherlands also concluded that the general surveillance plan submitted by the applicant is sufficient taking into account the intended uses of the product.

(6) The assessment report was submitted to the Commission and the competent authorities of the other Member States, some of which raised and maintained objections to the placing on the market of the product.

(7) The opinion of the European Food Safety Authority (EFSA), published on 12 December 2014, concluded, from all evidence provided, that there is no scientific reason to consider that the placing on the market of the genetically modified carnation (*Dianthus caryophyllus* L., line 25958) for ornamental use will cause any adverse effects on human health or the environment ([2]). EFSA also found that the scope of the monitoring plan provided by the notifier is in line with the intended use of the carnation.

(8) An examination of the full notification, additional information provided by the notifier, specific objections maintained by the Member States in the light of Directive 2001/18/EC, and the opinion of EFSA, discloses no reason to believe that the placing on the market of cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line 25958) will adversely affect human health or the environment in the context of its proposed ornamental use.

([1]) OJ L 106, 17.4.2001, p. 1.

([2]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on a notification (reference C/NL/09/01) for the placing on the market of the genetically modified carnation IFD-25958-3 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene. EFSA Journal 2014;12(12):3934, 19 pp. doi:10.2903/j.efsa.2014.3934.

(9) A unique identifier has been assigned to the genetically modified carnation (*Dianthus caryophyllus* L., line 25958) for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council [1] and Commission Regulation (EC) No 65/2004 [2].

(10) In light of the opinion of the European Food Safety Authority, it is not necessary to establish specific conditions for the intended use with regard to the handling or packaging of the product and the protection of particular ecosystems, environments or geographical areas.

(11) The proposed labelling, on a label or in an accompanying document, should include wording to inform operators and final users that the cut flowers of *Dianthus caryophyllus* L., line 25958 cannot be used for human or animal consumption nor for cultivation.

(12) A detection method as required by Annex III B.D.12 of Directive 2001/18/EC, was verified and tested for the *Dianthus caryophyllus* L., line 25958 by the European Union Reference Laboratory in December 2012.

(13) The Committee set up under Article 30(1) of Directive 2001/18/EC has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Consent**

Written consent shall be granted by the competent authority of the Netherlands to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified by Florigene Ltd, Melbourne, Australia (Reference C/NL/09/01).

The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, which are set out in Articles 3 and 4.

*Article 2*

**Product**

1. The genetically modified organisms to be placed on the market as product, hereinafter 'the product', are cut flowers of carnation (*Dianthus caryophyllus* L.), with modified flower colour, derived from a *Dianthus caryophyllus* L. cell culture, and transformed with *Agrobacterium tumefaciens*, strain AGL0, using the vector pCGP3366, and resulting in line 25958.

The product contains the following DNA in four cassettes:

(a) Cassette 1

The petunia *dfr* gene encoding dihydroflavonol 4-reductase (DFR), a key enzyme in the anthocyanin biosynthetic pathway, including its own promoter and terminator.

(b) Cassette 2

The promoter sequence from snapdragon chalcone synthase gene, flavonoid 3′5′-hydroxylase (*f3′5′h*) from *Viola hortensis* cDNA encoding F3′5′H, a key enzyme in the anthocyanin biosynthetic pathway, and the terminator from a petunia gene encoding a phospholipid transfer protein homologue.

[1] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[2] Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

(c) Cassette 3

The *Cauliflower mosaic virus* 35S promoter, a hairpin-forming construct consisting of a partial dihydroflavonol 4-reductase *dfr* sense and antisense fragment separated by a petunia *dfr* intron, targeted to specific, post-transcriptional down-regulation of endogenous carnation *dfr,* and the *CaMV* 35S terminator sequence.

These three cassettes were inserted into the plant genome to obtain the desired flower colour.

(d) Cassette 4

The *Cauliflower mosaic virus* 35S promoter, the 5′untranslated region of the petunia gene coding for chlorophyll a/b binding protein, the *SuRB* (*als*) gene coding for a mutant acetolactate synthase protein (ALS) derived from *Nicotiana tabacum* which confers tolerance to sulfonylurea, including its own terminator. This trait was used as a marker in the selection of transformants.

2. The consent shall cover progeny derived through vegetative reproduction of the genetically modified carnation (*Dianthus caryophyllus* L., line 25958).

*Article 3*

**Conditions for placing on the market**

The product may be placed on the market for ornamental use only and its cultivation is not allowed. The product may be placed on the market subject to the following conditions:

(a) In accordance with Article 19(3)(b) of Directive 2001/18/EC, the period of validity of the consent shall be 10 years starting from the date on which the consent is issued;

(b) The unique identifier of the product shall be IFD-25958-3;

(c) Without prejudice to Article 25 of Directive 2001/18/EC, the methodology for detecting and identifying the product, including experimental data demonstrating the specificity of the methodology as single-laboratory validated by the EU Reference Laboratory is publicly available at http://gmo-crl.jrc.ec.europa.eu/valid-2001-18.htm;

(d) Without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall, whenever requested to do so, make positive and negative control samples of the product, or its genetic material, or reference materials available to the competent authorities and to inspection services of Member States as well as to EU control laboratories;

(e) The words 'This product is a genetically modified organism' or 'This product is a genetically modified carnation', and the words 'not for human or animal consumption nor for cultivation' shall appear either on a label or in a document accompanying the product.

*Article 4*

**Monitoring**

1. Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan, contained in the notification and consisting of a general surveillance plan to check for any adverse effects on human health or the environment arising from handling or use of the products, is put in place and implemented.

The monitoring plan is available at [Link: *plan published on the internet*].

2. The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the product and of the conditions as to monitoring, including the appropriate management measures to be taken in case of accidental cultivation.

3. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of the monitoring activities.

4. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

(a) that the existing monitoring networks, including national botanic survey networks and plant protection services, as specified in the monitoring plan contained in the notification, gather the information relevant for the monitoring of the products; and

(b) that these existing monitoring networks referred to in point (a) have agreed to make available that information to the consent holder before the date of submission of the monitoring reports to the Commission and competent authorities of the Member States in accordance with paragraph 3.

*Article 5*

**Addressee**

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

# COMMISSION IMPLEMENTING DECISION (EU) 2015/693

## of 24 April 2015

## renewing the authorisation for existing genetically modified cotton MON 1445 (MON-Ø1445-2) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2766)*

**(Only the French and Dutch texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 11(3) and 23(3) thereof,

Whereas:

(1) Food additives, feed materials and feed additives produced from genetically modified cotton MON 1445 were placed on the market before the entry into force of Regulation (EC) No 1829/2003 and were notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation.

(2) On 17 April 2007, Monsanto Europe SA submitted to the Commission an application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 for the renewal of the authorisation for existing food additives, feed materials and feed additives produced from genetically modified cotton MON 1445 ('the application').

(3) On 16 June 2011, Monsanto Europe SA requested an extension of the scope of the application to include food cottonseed oil produced from genetically modified cotton MON 1445, which was previously notified as an existing product in accordance with Article 8(1)(a) of Regulation (EC) No 1829/2003.

(4) The scope of the application as extended covers the full range of current commercial uses of food and feed produced from cotton as defined in Articles 3(1)(c) and 15(1)(c) of Regulation (EC) No 1829/2003.

(5) On 16 December 2011, the European Food Safety Authority ('EFSA') gave a favourable opinion ([2]) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that products derived from genetically modified cotton MON 1445, as described in the application, are as safe as products derived from its conventional counterpart, in the context of their intended uses.

(6) EFSA concluded that the analysis of horizontal gene transfer from genetically modified cotton MON 1445 to bacteria did not indicate a risk to human or animal health or to the environment in the context of its intended uses, considering the expected low frequency of gene transfer from plant to bacteria compared with that between bacteria, and the very low exposure to DNA from genetically modified cotton MON 1445.

(7) EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(8) Consequently, authorisation should be renewed for the products produced from genetically modified cotton MON 1445.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion on application EFSA-GMO-RX-MON1445 for renewal of the authorisation for continued marketing of existing cottonseed oil, food additives, feed materials and feed additives produced from cotton MON 1445 that were notified under Articles 8(1)(a), 8(1)(b) and 20(1)(b) of Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2011; 9(12):2479. [1-28] doi:10.2903/j.efsa.2011.2479.

(9) A unique identifier should be assigned to each genetically modified organism as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(10) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed produced from genetically modified cotton MON 1445.

(11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([2]).

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.) MON 1445, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-Ø1445-2, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Renewal of authorisation**

The authorisation for the placing on the market of the following products is renewed for the purposes of Articles 11 and 23 of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) food produced from MON-Ø1445-2 cotton;

(b) feed produced from MON-Ø1445-2 cotton.

*Article 3*

**Labelling**

For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'cotton'.

*Article 4*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([2]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 5*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe SA, Belgium, representing Monsanto Company, United States of America.

*Article 6*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 7*

**Addressee**

This Decision is addressed to Monsanto Europe SA, Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder**

Name: Monsanto Europe SA

Address: Avenue de Tervuren 270-272, 1150 Brussels, Belgium

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.

(b) **Designation and specification of the products**

1. Food produced from MON-Ø1445-2 cotton.
2. Feed produced from MON-Ø1445-2 cotton.

The genetically modified MON-Ø1445-2 cotton, as described in the application, expresses the CP4 EPSPS protein which confers tolerance to glyphosate-containing herbicides. An *npt*II gene, conferring kanamycin and neomycin resistance, and *aad*A gene, conferring spectinomycin and streptomycin resistance, were used as selective markers in the genetic modification process.

(c) **Labelling**

For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'cotton'.

(d) **Method for detection**

1. Event-specific real-time PCR based method for the quantification of MON-Ø1445-2 cotton.
2. Validated on genomic DNA, extracted from seeds, by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm
3. Reference Material: AOCS 0804-B and AOCS 0804-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON-Ø1445-2

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Not applicable.

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan for environmental effects**

Not required.

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/694

## of 24 April 2015

## concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a carnation (*Dianthus caryophyllus* L., line 26407) genetically modified for flower colour

*(notified under document C(2015) 2768)*

**(Only the Dutch text is authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ([1]), and in particular the first subparagraph of Article 18(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority of the Member State that received the notification for the placing on the market of that product, in accordance with the procedure laid down in that Directive.

(2) A notification concerning the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line 26407) was submitted by Florigene Ltd, Melbourne, Australia, to the competent authority of the Netherlands in March 2009.

(3) The notification covers import, distribution and retailing of cut flowers of *Dianthus caryophyllus* L., line 26407 as for any other carnation.

(4) In accordance with the procedure established by Article 14 of Directive 2001/18/EC, the competent authority of the Netherlands prepared an assessment report, which concluded that no reasons have emerged on the basis of which consent for the placing on the market of cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line 26407) for ornamental use should be withheld, if specific conditions are fulfilled.

(5) In its assessment report, the competent authority of the Netherlands also concluded that the general surveillance plan submitted by the applicant is sufficient taking into account the intended uses of the product.

(6) The assessment report was submitted to the Commission and the competent authorities of the other Member States, some of which raised and maintained objections to the placing on the market of the product.

(7) The opinion of the European Food Safety Authority (EFSA), published on 12 December 2014, concluded that, from all evidence provided, there is no scientific reason to consider that the placing on the market of the genetically modified carnation (*Dianthus caryophyllus* L., line 26407) for ornamental use will cause any adverse effects on human health or the environment ([2]). EFSA also found that the scope of the monitoring plan provided by the notifier is in line with the intended use of the carnation.

([1]) OJ L 106, 17.4.2001, p. 1.

([2]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2014. Scientific Opinion on a notification (reference C/NL/09/02) for the placing on the market of the genetically modified carnation IFD-26407-2 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene. EFSA Journal 2014;12(12):3935, 18 pp. doi:10.2903/j.efsa.2014.3935.

(8) An examination of the full notification, additional information provided by the notifier, specific objections maintained by the Member States in the light of Directive 2001/18/EC, and the opinion of EFSA, discloses no reason to believe that the placing on the market of cut flowers of the genetically modified carnation (*Dianthus caryophyllus* L., line 26407) will adversely affect human health or the environment in the context of its proposed ornamental use.

(9) A unique identifier has been assigned to the genetically modified carnation (*Dianthus caryophyllus* L., line 26407) for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council [1] and Commission Regulation (EC) No 65/2004 of 14 January 2004 [2].

(10) In light of the opinion of the European Food Safety Authority, it is not necessary to establish specific conditions for the intended use with regard to the handling or packaging of the product and the protection of particular ecosystems, environments or geographical areas.

(11) The proposed labelling, on a label or in an accompanying document, should include wording to inform operators and final users that the cut flowers of *Dianthus caryophyllus* L., line 26407 cannot be used for human or animal consumption, nor for cultivation.

(12) A detection method as required by Annex III B.D.12 of Directive 2001/18/EC, was verified and tested for the *Dianthus caryophyllus* L., line 26407 by the European Union Reference Laboratory in November 2013.

(13) The Committee set up under Article 30(1) of Directive 2001/18/EC has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Consent**

Written consent shall be granted by the competent authority of the Netherlands to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified by Florigene Ltd, Melbourne, Australia (Reference C/NL/09/02).

The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, which are set out in Articles 3 and 4.

*Article 2*

**Product**

1. The genetically modified organisms to be placed on the market as product, hereinafter 'the product', are cut flowers of carnation (*Dianthus caryophyllus* L.), with modified flower colour, derived from a *Dianthus caryophyllus* L. cell culture, and transformed with *Agrobacterium tumefaciens*, strain AGL0, using the vector pCGP2355, and resulting in line 26407.

The product contains the following DNA in three cassettes:

(a) Cassette 1

The promoter from snapdragon chalcone synthase gene, the petunia cytochrome b5 *(difF)* cDNA encoding a cytochrome b5 protein to enhance activity of F3′5′H, and the terminator from a petunia gene encoding a phospholipid transfer protein homologue.

[1] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[2] Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

(b) Cassette 2

The petunia flavonoid 3′5′-hydroxylase cDNA (*f3′5′h*) encoding F3′5′H, a key enzyme in the anthocyanin biosynthetic pathway and the promoter and terminator of a *Dianthus caryophyllus* anthocyanidin synthase (*ans*) gene.

These two cassettes were inserted into the plant genome to obtain the desired flower colour.

(c) Cassette 3

The *Cauliflower mosaic virus* 35S promoter, the 5'untranslated region of the petunia gene coding for chlorophyll a/b binding protein, the *SuRB* (*als*) gene coding for a mutant acetolactate synthase protein (ALS) derived from *Nicotiana tabacum*, which confers tolerance to sulfonylurea. This trait was used as a marker in the selection of transformants.

2. The consent shall cover progeny derived through vegetative reproduction of the genetically modified carnation (*Dianthus caryophyllus* L., line 26407).

*Article 3*

**Conditions for placing on the market**

The product may be placed on the market for ornamental use only and its cultivation is not allowed. The product may be placed on the market subject to the following conditions:

(a) In accordance with Article 19(3)(b) of Directive 2001/18/EC, the period of validity of the consent shall be 10 years starting from the date on which the consent is issued;

(b) The unique identifier of the product shall be IFD-26407-2;

(c) Without prejudice to Article 25 of Directive 2001/18/EC, the methodology for detecting and identifying the product, including experimental data demonstrating the specificity of the methodology as single-laboratory validated by the European Union Reference Laboratory is publicly available at http://gmo-crl.jrc.ec.europa.eu/valid-2001-18.htm;

(d) Without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall, whenever requested to do so, make positive and negative control samples of the product, or its genetic material, or reference materials available to the competent authorities and to inspection services of Member States as well as to EU control laboratories;

(e) The words 'This product is a genetically modified organism' or 'This product is a genetically modified carnation', and the words 'not for human or animal consumption nor for cultivation' shall appear either on a label or in a document accompanying the product.

*Article 4*

**Monitoring**

1. Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan, contained in the notification and consisting of a general surveillance plan to check for any adverse effects on human health or the environment arising from handling or use of the products, is put in place and implemented.

The monitoring plan is available at [Link: *plan published on the internet*].

2. The consent holder shall directly inform the operators and users concerning the safety and general characteristics of the product and of the conditions as to monitoring, including the appropriate management measures to be taken in case of accidental cultivation.

3. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of the monitoring activities.

4. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

(a) that the existing monitoring networks, including national botanic survey networks and plant protection services, as specified in the monitoring plan contained in the notification, gather the information relevant for the monitoring of the products; and

(b) that these existing monitoring networks referred to in point (a) have agreed to make available that information to the consent holder before the date of submission of the monitoring reports to the Commission and competent authorities of the Member States in accordance with paragraph 3.

*Article 5*

**Addressee**

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

# COMMISSION IMPLEMENTING DECISION (EU) 2015/695

## of 24 April 2015

## renewing the authorisation for existing genetically modified cotton MON 531 x MON 1445 (MON-ØØ531-6 x MON-Ø1445-2) products and authorising the placing on the market of cottonseed oil produced from genetically modified cotton MON 531 x MON 1445 (MON-ØØ531-6 x MON-Ø1445-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2769)*

**(Only the French and Dutch texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1], and in particular Articles 7(3), 11(3), 19(3) and 23(3) thereof,

Whereas:

(1) On 30 November 2004, Monsanto Europe S.A. submitted to the competent authority of the United Kingdom an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 for the placing on the market of food and feed cottonseed oil and its constituents produced from genetically modified cotton MON 531 x MON 1445.

(2) Food additives, feed materials and feed additives produced from genetically modified cotton MON 531 x MON 1445 were placed on the market before the entry into force of Regulation (EC) No 1829/2003 and were notified as existing products in accordance with Articles 8(1)(b) and 20(1)(b) of that Regulation.

(3) On 17 April 2007, Monsanto Europe S.A. submitted to the Commission an application in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003 for the renewal of the authorisation for existing food additives, feed materials and feed additives produced from genetically modified cotton MON 531 x MON 1445 cotton.

(4) The scope of the two applications, taken together, covers the full range of current commercial uses of food and feed produced from cotton as defined in Articles 3(1)(c) and 15(1)(c) of Regulation (EC) No 1829/2003.

(5) On 28 March 2012, the European Food Safety Authority ('EFSA') gave a favourable opinion [2] in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that products derived from genetically modified cotton MON 531 x MON 1445 are as safe as products derived from the conventional counterpart, in the context of their intended uses.

(6) EFSA concluded that the analysis of horizontal gene transfer from genetically modified cotton MON 531 x MON 1445 to bacteria did not indicate a risk to human or animal health or to the environment in the context of its intended uses, considering the expected low frequency of gene transfer from plant to bacteria compared with that between bacteria, and the very low exposure to DNA from genetically modified cotton MON 531 x MON 1445.

(7) EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(8) Consequently, authorisation should be granted for the products produced from genetically modified cotton MON 531 x MON 1445.

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[1] OJ L 268, 18.10.2003, p. 1.

[2] Scientific Opinion on applications EFSA-GMO-UK-2005-09 and EFSA-GMO-RX-MON531×MON1445 for the placing on the market of food and feed produced from or containing ingredients produced from insect-resistant and herbicide-tolerant genetically modified cotton MON 531 × MON 1445; and for the renewal of authorisation of existing products produced from cotton MON 531 × MON 1445, both under Regulation (EC) No 1829/2003 from Monsanto. The EFSA Journal (2012);10(3):2608. doi:10.2903/j.efsa.2012.2608.

(9) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 [1].

(10) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed produced from genetically modified cotton MON 531 x MON 1445.

(11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council [2].

(13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified cotton (*Gossypium hirsutum* L. and *Gossypium barbadense* L.) MON 531 x MON 1445, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ531-6 x MON-Ø1445-2, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) food produced from MON-ØØ531-6 x MON-Ø1445-2 cotton;

(b) feed produced from MON-ØØ531-6 x MON-Ø1445-2 cotton.

*Article 3*

**Labelling**

For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'cotton'.

*Article 4*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

[1] Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

[2] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 5*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

*Article 6*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 7*

**Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, B-1150 Brussels — Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holder**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, B-1150 Brussels — Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States of America.

(b) **Designation and specification of the products**

1. Food produced from MON-ØØ531-6 x MON-Ø1445-2 cotton.
2. Feed produced from MON-ØØ531-6 x MON-Ø1445-2 cotton.

The genetically modified MON-ØØ531-6 x MON-Ø1445-2 cotton, as described in the application, expresses the Cry1Ac protein which confers resistance to lepidopteran pests and the CP4 EPSPS protein which confers tolerance to glyphosate-containing herbicides. An *npt*II gene, conferring kanamycin and neomycin resistance, and *aad*A gene, conferring spectinomycin and streptomycin resistance, were used as selective markers in the genetic modification process.

(c) **Labelling**

For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, the 'name of the organism' shall be 'cotton'.

(d) **Method for detection**

1. Event specific real-time PCR based method for the quantification of MON-ØØ531-6 x MON-Ø1445-2 cotton
2. Validated on genomic DNA, extracted from seeds, by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm
3. Reference Material: AOCS 0804-B, AOCS 0804-C and AOCS 0804-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON-ØØ531-6 x MON-Ø1445-2

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Not applicable.

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan for environmental effects**

Not required.

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/696

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87705 (MON-877Ø5-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2770)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3) and Article 19(3) thereof,

Whereas:

(1) On 18 February 2010, Monsanto Europe SA submitted to the competent authority of The Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from soybean MON87705 ('the application').

(2) The application also covers the placing on the market of soybean MON87705 in products consisting of it or containing it for any other uses than food and feed as any other soybean, with the exception of cultivation.

(3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 30 October 2012, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). It concluded that soybean MON87705, as described in the application, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment in the context of its intended uses as proposed by the applicant. These uses covered all food and feed uses as any conventional soybean except for the commercial frying uses of the oil.

(5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.

(6) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(7) Subsequently, the Commission mandated EFSA to complement its opinion to include commercial frying uses of the oil derived from MON87705, requesting the necessary information from the applicant, if needed.

([1]) OJ L 268, 18.10.2003, p. 1.

([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2012. Scientific Opinion on application EFSA-GMO-NL-2010-78 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean MON87705 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. *EFSA Journal* 2012; 10(10):2909, 34 pp. doi:10.2903/j.efsa.2012.2909.

(8) On 17 December 2013, EFSA issued a statement ([1]), complementing its initial opinion with the oil derived from MON87705 soybean for commercial frying and concluded that the updated nutritional assessment covering all food uses of soybean MON87705 oil does not impact on human health and nutrition.

(9) In addition to that, EFSA recommended in this complementing statement a post-market monitoring plan to be implemented, focusing on the collection of consumption data for the European population.

(10) Taking into account those considerations, authorisation should be granted to the products.

(11) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([2]).

(12) Food, food ingredients and feed containing, consisting of, or produced from MON87705 soybean should be labelled in accordance with the requirements provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003.

(13) On the basis of the EFSA opinion, confirming that fatty acid composition of the seeds of MON87705 soybean and derived oil has been changed in relation to the conventional counterpart, a specific labelling appears to be necessary in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003.

(14) In order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO for which authorisation is requested, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(15) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([3]) lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(16) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([4]). The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(17) The authorisation holder should also submit annual reports on the implementation and the results of the activities set out in the post-market monitoring plan.

(18) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(19) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and point (c) of Article 15(2) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([5]).

(20) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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([1]) EFSA GMO Panel, 2013. Statement complementing the scientific opinion on application EFSA-GMO-NL-2010-78 to cover the safety of soybean MON87705 oil for commercial frying. *EFSA Journal* 2013; 11(12):3507, 9pp. doi:10.2903/j.efsa.2013.3507.

([2]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([3]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([4]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([5]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified MON87705 soybean (*Glycine max* (L.) Merr.), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-877Ø5-6, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-877Ø5-6 soybean;

(b) feed containing, consisting of, or produced from MON-877Ø5-6 soybean;

(c) MON-877Ø5-6 soybean in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.

3. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of MON-877Ø5-6 soybean with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003**

1. The authorisation holder shall ensure that the post-market monitoring plan of the MON-877Ø5-6 soybean oil, as set out in point (g) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the post-market monitoring plan for the duration of the authorisation.

*Article 6*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe SA, Belgium, representing Monsanto Company, United States.

*Article 8*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9*

**Addressee**

This Decision is addressed to Monsanto Europe SA, Avenue de Tervuren 270-272, 1150 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder:**

Name: Monsanto Europe SA

Address: Avenue de Tervuren 270-272, 1150 Brussels, Belgium

On behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.

(b) **Designation and specification of the products:**

1. foods and food ingredients containing, consisting of, or produced from MON-877Ø5-6 soybean;

2. feed containing, consisting of, or produced from MON-877Ø5-6 soybean;

3. MON-877Ø5-6 soybean in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified MON-877Ø5-6 soybean, as described in the application, has a reduced expression of fatty acid Δ12-desaturase (FAD2) and palmitoyl acyl carrier protein thioesterase (FATB) enzymes, which results in increased oleic acid and reduced linoleic acid profile and expresses a CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides.

(c) **Labelling:**

1. For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.

3. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-877Ø5-6 soybean with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

1. Event-specific real-time PCR based method for the quantification of MON-877Ø5-6 soybean.

2. Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from soybean seeds, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

3. Reference Material: AOCS 0210-A and AOCS 0906-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier:**

MON-877Ø5-6

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Biosafety Clearing-House, Record ID: see (*to be completed when notified*).

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

*Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003*

1. The authorisation holder shall collect the following information:

   (i) quantities of MON-877Ø5-6 soybean oil and MON-877Ø5-6 soybeans for oil extraction, imported into the European Union for the placing on the market as or in products for food;

   (ii) in case of import of products mentioned under (i), results of database searches in the FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed.

2. The authorisation holder shall, based on the information collected and reported, review the nutritional assessment conducted as part of the risk assessment.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(Link: *plan published on the internet*)

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/697

## of 24 April 2015

## authorising the placing on the market of genetically modified maize T25 (ACS-ZMØØ3-2) and renewing the existing maize T25 (ACS-ZMØØ3-2) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2772)*

**(Only the German text is authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3), Article 11(3), Article 19(3) and Article 23(3) thereof,

Whereas:

(1) On 17 April 2007, Bayer CropScience submitted to the competent authority of The Netherlands an application, in accordance with Article 5 and Article 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from T25 maize.

(2) The application also covers the placing on the market of T25 maize in products consisting of it or containing it for any other uses than food and feed as any other maize, including the seeds for cultivation.

(3) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 17 April 2007, Bayer CropScience submitted to the European Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation of food and food ingredients produced from T25 maize, feed containing and consisting of genetically modified T25 maize, feed produced from T25 maize (feed materials and feed additives) and seeds from T25 maize for cultivation which were previously notified as existing products in accordance with Article 8(1)(a) and Article 20(1)(a) of that Regulation.

(5) On 11 January 2013, Bayer CropScience informed the European Commission of its decision to amend the scope of the above-mentioned applications to no longer include the authorisation of seeds from T25 maize for cultivation in the European Union.

(6) On 3 October 2013, the European Food Safety Authority ('EFSA') gave a favourable opinion for both new and renewal applications in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that T25 maize, as described in the applications, is as safe as its conventional counterpart with respect to potential effects on human and animal health and the environment, in the context of its intended use ([3]). In its opinion, EFSA also considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of that Regulation.

(7) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
([3]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00761

(8) Taking into account those considerations, authorisation should be granted for the products.

(9) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(10) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from T25 maize. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO with the exception of food products for which authorisation is requested should be complemented by a clear indication that the products in question must not be used for cultivation.

(11) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]), lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(12) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(13) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(14) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([4]).

(15) The applicant has been consulted on the measures provided for in this Decision.

(16) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified maize (*Zea mays* L.) T25, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier ACS-ZMØØ3-2, as provided for in Regulation (EC) No 65/2004.

([1]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([2]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([3]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

([4]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from ACS-ZMØØ3-2 maize;

(b) feed containing, consisting of, or produced from ACS-ZMØØ3-2 maize;

(c) ACS-ZMØØ3-2 maize in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.

2. The words 'not for cultivation' shall appear on the label and in the documents accompanying the products containing or consisting of ACS-ZMØØ3-2 maize with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Bayer CropScience AG.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Bayer CropScience AG, Alfred-Nobel-Strasse 50, D — 40789 Monheim am Rhein — Germany.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holder:**

Name: Bayer CropScience AG

Address: Alfred-Nobel-Strasse 50, D — 40789 Monheim am Rhein — Germany

(b) **Designation and specification of the products:**

1. foods and food ingredients containing, consisting of, or produced from ACS-ZMØØ3-2 maize;
2. feed containing, consisting of, or produced from ACS-ZMØØ3-2 maize;
3. ACS-ZMØØ3-2 maize in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified ACS-ZMØØ3-2 maize, as described in the application, expresses the PAT protein which confers tolerance to glufosinate-ammonium herbicides.

(c) **Labelling:**

1. For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize';
2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of ACS-ZMØØ3-2 maize with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

— Event specific real-time PCR based method for the quantification of ACS-ZMØØ3-2 maize;

— Validated on DNA extracted from leaves by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdoss.htm

— Reference Material: AOCS 0306-H and AOCS 0306-C are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier:**

ACS-ZMØØ3-2

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

Biosafety Clearing-House [to be entered in the EU register of genetically modified food and feed when notified].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC [to be entered in the EU register of genetically modified food and feed when notified].

(i) **Post market monitoring requirements for the use of the food for human consumption:**

Not required.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/698

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2773)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 14 June 2007, Pioneer Overseas Corporation submitted to the competent authority of the Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from 305423 soybean ('the application').

(2) The application also covers the placing on the market of 305423 soybean in products consisting of it or containing it for any other uses than food and feed as any other soybean, with the exception of cultivation.

(3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 18 December 2013, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). It concluded that 305423 soybean, as described in the application, is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment in the context of its intended uses.

(5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(6) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products. In addition, EFSA recommended a post-market monitoring plan to be implemented, focusing on the collection of consumption data for the European population.

(7) Taking into account those considerations, authorisation should be granted to the products.

(8) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([4]).

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on application EFSA-GMO-NL-2007-45 for the placing on the market of herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer. *EFSA Journal* 2013;11(12):3499, 35 pp. doi:10.2903/j.efsa.2013.3499.
([4]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

(9) Food, food ingredients and feed containing, consisting of, or produced from soybean 305423 should be labelled in accordance with the requirements provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003.

(10) On the basis of the EFSA opinion, confirming that fatty acid composition of the seeds of soybean 305423 and derived oil has been changed in relation to the conventional counterpart, a specific labelling appears to be necessary in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003.

(11) In order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO for which authorisation is requested, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(12) Regulation (EC) No 1830/2003 of the European Parliament and of the Council [1] lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(13) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC [2]. The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(14) The authorisation holder should also submit annual reports on the implementation and the results of the activities set out in the post-market monitoring plan.

(15) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(16) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and point (c) of Article 15(2) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council [3].

(17) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified 305423 soybean (*Glycine max* (L.) Merr.), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DP-3Ø5423-1, as provided for in Regulation (EC) No 65/2004.

[1] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[2] Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

[3] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from DP-3Ø5423-1 soybean;

(b) feed containing, consisting of, or produced from DP-3Ø5423-1 soybean;

(c) DP-3Ø5423-1 soybean in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. For the purposes of the labelling requirements laid down in Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.

3. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DP-3Ø5423-1 soybean with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003**

1. The authorisation holder shall ensure that the post-market monitoring plan of the DP-3Ø5423-1 soybean oil, as set out in point (g) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the post-market monitoring plan for the duration of the authorisation.

*Article 6*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7*

**Authorisation holder**

The authorisation holder shall be Pioneer Overseas Corporation.

*Article 8*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9*

**Addressee**

This Decision is addressed to Pioneer Overseas Corporation, Avenue des Arts 44, 1040 Brussels, Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder**

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, 1040 Brussels — Belgium

On behalf of Pioneer Hi-Bred International, Inc. — 7100 NW 62nd Avenue — P.O. Box 1014 — Johnston, IA 50131-1014 — United States of America.

(b) **Designation and specification of the products**

1. Foods and food ingredients containing, consisting of, or produced from DP-3Ø5423-1 soybean.
2. Feed containing, consisting of, or produced from DP-3Ø5423-1 soybean.
3. DP-3Ø5423-1 soybean in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified DP-3Ø5423-1 soybean, as described in the application, has a reduced expression of the soybean enzyme omega-6 desaturase, which results in a high oleic acid and reduced linoleic acid profile, and expresses an optimised *Glycine max-hra* gene, which confers tolerance to acetolactate synthase-inhibiting herbicides.

(c) **Labelling**

1. For the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.
2. For the purposes of the labelling requirements laid down in Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.
3. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of DP-3Ø5423-1 soybean with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— Event specific real-time PCR based method for the quantification of DP-3Ø5423-1 soybean.

— Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from soybean seeds, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

— Reference Material: ERM-BF426 accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

(e) **Unique identifier**

DP-3Ø5423-1

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

*Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003*

1. The authorisation holder shall collect the following information:
   (i) quantities of DP-3Ø5423-1 soybean oil and 305423 soybeans for oil extraction, imported into the European Union for the placing on the market as or in products for food;
   (ii) in case of import of products mentioned under (i), results of database searches in FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed.

2. The authorisation holder shall, based on the information collected and reported, review the nutritional assessment conducted as part of the risk assessment.

(h) **Monitoring plan for environmental effects**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/699

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton T304-40 (BCS-GHØØ4-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2782)*

**(Only the German text is authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 29 March 2011, Bayer CropScience AG submitted to the competent authority of the Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from T304-40 cotton ('the application').

(2) The application also covers the placing on the market of T304-40 cotton in products consisting of it or containing it for other uses than food and feed as any other cotton, with the exception of cultivation.

(3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 20 June 2013, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that T304-40 cotton, as described in the application, is as safe as its non-genetically modified counterpart with respect to potential effects on human and animal health or the environment in the context of its intended uses ([3]).

(5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.

(6) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(7) Taking into account those considerations, authorisation should be granted to the products.

(8) A unique identifier should be assigned to each genetically modified organism ('GMO') as provided for in Commission Regulation (EC) No 65/2004 ([4]).

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
([3]) EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on application EFSA-GMO-NL-2011-97 for the placing on the market of insect-resistant and herbicide-tolerant genetically modified cotton T304-40 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience AG. EFSA Journal 2013; 11(6):3251, 31 pp. doi:10.2903/j.efsa.2013.3251.
([4]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

(9) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from T304-40 cotton. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO for which authorisation is requested, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(10) Regulation (EC) No 1830/2003 of the European Parliament and of the Council [1] lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(11) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC [2]. The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(12) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and point (c) of Article 15(2) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council [3].

(14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified cotton (*Gossypium hirsutum*) T304-40, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ4-7, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from BCS-GHØØ4-7 cotton;

(b) feed containing, consisting of, or produced from BCS-GHØØ4-7 cotton;

(c) BCS-GHØØ4-7 cotton in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

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[1] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[2] Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

[3] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of T304-40 cotton with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Bayer CropScience AG.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Bayer CropScience AG, Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein, Germany.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holder**

Name: Bayer CropScience AG

Address: Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein — Germany

(b) **Designation and specification of the products**

(1) foods and food ingredients containing, consisting of, or produced from BCS-GHØØ4-7 cotton;

(2) feed containing, consisting of, or produced from BCS-GHØØ4-7 cotton;

(3) BCS-GHØØ4-7 cotton in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified T304-40 cotton, as described in the application, expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and PAT protein which confers tolerance to glufosinate ammonium-based herbicides.

(c) **Labelling**

(1) for the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton';

(2) the words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of T304-40 cotton with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— event-specific real-time PCR-based method for the quantification of T304-40 cotton,

— validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

Reference Material: ERM-BF429 accessible via the Joint Research Centre (JRC) of the European Commission, the Institute for Reference Materials and Measurements (IRMM) at http://www.irmm.jrc.be/html/reference_materials_catalogue/index.htm

(e) **Unique identifier**

BCS-GHØØ4-7

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/700

## of 24 April 2015

## authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON87708 (MON-877Ø8-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2785)*

**(Only the French and Dutch texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 2 February 2011, Monsanto Europe S.A. submitted to the competent authority of the Netherlands an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from soybean MON87708 ('the application').

(2) The application also covers the placing on the market of soybean MON87708 in products consisting of it or containing it for any other uses than food and feed as any other soybean, with the exception of cultivation.

(3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 3 October 2013, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that soybean MON87708, as described in the application, is as safe as its non-genetically modified counterpart and reference varieties with respect to potential effects on human and animal health or the environment, in the context of its intended uses ([3]).

(5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of that Regulation.

(6) In its opinion, EFSA also concluded that the environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(7) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified soybean MON87708.

(8) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([4]).

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
([3]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00760
([4]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

(9) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from soybean MON87708. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO for which authorisation is requested, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.

(10) Regulation (EC) No 1830/2003 of the European Parliament and of the Council [1] lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(11) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC [2]. The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.

(12) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

(13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council [3].

(14) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifier**

Genetically modified soybean (*Glycine max* (L.) Merr.) MON87708, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-877Ø8-9, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from soybean MON-877Ø8-9;

(b) feed containing, consisting of, or produced from soybean MON-877Ø8-9;

(c) soybean MON-877Ø8-9 in products containing it or consisting of it for any other use than (a) and (b), with the exception of cultivation.

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[1] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

[2] Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

[3] Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 3*

**Labelling**

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of soybean MON-877Ø8-9 with the exception of products referred to in point (a) of Article 2.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 6*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, B-1150 Brussels — Belgium.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and Authorisation holder**

Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, B-1150 Brussels — Belgium

On behalf of Monsanto Company — 800 N. Lindbergh Boulevard — St. Louis, Missouri 63167 — United States of America.

(b) **Designation and specification of the products**

(1) foods and food ingredients containing, consisting of, or produced from soybean MON-877Ø8-9;

(2) feed containing, consisting of, or produced from soybean MON-877Ø8-9;

(3) soybean MON-877Ø8-9 in products containing it or consisting of it for any other use than 1 and 2, with the exception of cultivation.

The genetically modified soybean MON-877Ø8-9, as described in the application, expresses the DMO (dicamba mono-oxygenase) proteins which confer tolerance to dicamba-based herbicides.

(c) **Labelling**

(1) for the purposes of the specific labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean';

(2) the words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of soybean MON-877Ø8-9 with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection**

— event-specific real-time PCR based method for the quantification of soybean MON-877Ø8-9,

— validated on genomic DNA, extracted from seeds, by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

— Reference Material: AOCS 0311-A and AOCS 0906-A are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON-877Ø8-9

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House, Record ID: see [*to be completed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published on the internet*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

*Note:* Links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

# COMMISSION IMPLEMENTING DECISION (EU) 2015/701

## of 24 April 2015

## authorising the placing on the market of food containing or consisting of genetically modified oilseed rape GT73, or food and feed produced from that genetically modified organism pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

*(notified under document C(2015) 2786)*

**(Only the Dutch and French texts are authentic)**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Article 7(3), Article 11(3), Article 19(3) and Article 23(3) thereof,

Whereas:

(1) On 17 and 18 April 2007, Monsanto Europe SA submitted to the Commission applications, in accordance with Article 8(4) and Article 20(4) of Regulation (EC) No 1829/2003, for renewal of the authorisations of existing food and feed produced from GT73 oilseed rape. The scope of the two renewal applications covers the continued marketing of existing food produced from oilseed rape GT73 (refined oil and food additives) and existing feed produced from oilseed rape GT73 (feed materials and feed additives) which were lawfully placed on the market in the Community before the date of entry into force of Regulation (EC) No 1829/2003. After the date of the entry into force of Regulation (EC) No 1829/2003, these products were notified to the European Commission according to Articles 8(1)(a), 8(1)(b) and 20(1)(b) of that Regulation and included in the Community Register of genetically modified food and feed.

(2) On 15 December 2009, the European Food Safety Authority ('EFSA') gave a favourable opinion on the renewal application in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that it is unlikely that the continued marketing of the food and feed produced from oilseed rape GT73 as described in the application will have any adverse effects on human or animal health or the environment, in the context of their intended uses ([2]).

(3) On 26 August 2010, Monsanto Europe SA submitted to the competent authority of the Netherlands an application, in accordance with Article 5 of Regulation (EC) No 1829/2003, for the placing on the market of foods and food ingredients containing, consisting of, or produced from oilseed rape GT73 (including pollen of oilseed rape GT73 and the accidental unintentional presence of viable seeds), with the exception of processed oil and food additives. The application does not include cultivation in the EU.

(4) In accordance with Article 5(5) of Regulation (EC) No 1829/2003, that application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([3]), and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(5) On 12 February 2013, EFSA gave a favourable opinion on the new application in accordance with Article 6 Regulation (EC) No 1829/2003. It concluded that there is no indication of safety concerns for the human health in the context of the uses covered by the application, and in particular in either oilseed rape GT73 pollen/pollen-containing dietary supplements or the adventitious presence of trace levels of seeds in human foods ([4]). However, due to the lack of availability of relevant consumption and safety data, EFSA could not perform an equivalent

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00952
http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2009-00953
([3]) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).
([4]) http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00078

assessment with isolated seed protein. EFSA also concluded that the environmental risk assessment of GT73 did not identify any safety concerns, in the context of its intended uses.

(6) On 19 March 2013, the Commission asked EFSA to complete its assessment to cover all possible uses of oilseed rape GT73 requested in the application.

(7) Subsequently, on 8 May 2013, Monsanto Europe SA informed the Commission that it does not intend to market isolated protein products from GT73 in the EU. Taking into account the fact that this particular use is very limited and accidental presence of the isolated seed protein in the food chain is very unlikely, it could be excluded from the scope of this Decision.

(8) In both opinions, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultations of the national competent authorities as provided for in Article 6(4) of Regulation (EC) No 1829/2003.

(9) The environmental monitoring plan, consisting of a general surveillance plan, submitted by the applicant is in line with the intended uses of the products.

(10) The use of feed containing or consisting of GT73 oilseed-rape and products other than food and feed containing it or consisting of it with the exception of cultivation, has already been authorised by Commission Decision 2005/635/EC ([1]).

(11) Taking into account those considerations, authorisation (renewal and new authorisation) should be granted to the foods and food ingredients containing, consisting of GT73 oilseed rape, with the exception of isolated seed protein, and to the food and feed produced from GT73 oilseed rape.

(12) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([2]).

(13) On the basis of the two EFSA opinions, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients containing or consisting of, and food and feed produced from oilseed rape GT73.

(14) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([3]), lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for products containing or consisting of GMOs are laid down in paragraphs 1 to 5 of Article 4 of that Regulation and those for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(15) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with Commission Decision 2009/770/EC ([4]). The EFSA opinions do not justify the imposition of specific conditions or restrictions for the placing on the market and/or specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and in Article 18(5) of Regulation (EC) No 1829/2003.

(16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.

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([1]) Commission Decision 2005/635/EC of 31 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of an oilseed rape product (*Brassica napus* L., GT73 line) genetically modified for tolerance to the herbicide glyphosate (OJ L 228, 3.9.2005, p. 11).

([2]) Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

([3]) Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

([4]) Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

(17) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and point (c) of Article 15(2) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ([1]).

(18) The applicant has been consulted on the measures provided for in this Decision.

(19) The Standing Committee on the Food Chain and Animal Health has not delivered an opinion within the time limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

*Article 1*

**Genetically modified organism and unique identifiers**

Genetically modified oilseed rape (*Brassica napus* L.) GT73, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØØ73-7, as provided for in Regulation (EC) No 65/2004.

*Article 2*

**Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

(a) foods and food ingredients containing, consisting of, or produced from MON-ØØØ73-7 oilseed rape, with the exception of isolated seed protein;

(b) feed produced from MON-ØØØ73-7 oilseed rape.

*Article 3*

**Labelling**

For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'oilseed rape'.

*Article 4*

**Monitoring for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

*Article 5*

**Community register**

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

([1]) Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 6*

**Authorisation holder**

The authorisation holder shall be Monsanto Europe SA, Belgium, representing Monsanto Company, United States of America.

*Article 7*

**Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 8*

**Addressee**

This Decision is addressed to Monsanto Europe SA, Belgium, Avenue de Tervueren 270-272, 1150 Brussels, Belgium, representing Monsanto Company, 800 N. Lindbergh Boulevard St. Louis, Missouri 63167, United States of America.

Done at Brussels, 24 April 2015.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

(a) **Applicant and authorisation holder**

Name: Monsanto Europe SA, Belgium

Address: Avenue de Tervueren 270-272, 1150 Brussels, Belgium

on behalf of Monsanto Company, 800 N. Lindbergh Boulevard, St. Louis, Missouri 63167, United States of America.

(b) **Designation and specification of the products**

1. foods and food ingredients containing, consisting of, or produced from MON-ØØØ73-7 oilseed rape, with the exception of isolated seed protein;
2. feed produced from MON-ØØØ73-7 oilseed rape.

The genetically modified MON-ØØØ73-7 oilseed rape, as described in the applications, expresses the CP4 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) and glyphosate oxidoreductase variant 247 (GOXv247) proteins which confer tolerance to glyphosate-based herbicides.

(c) **Labelling**

For the purposes of the specific labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'oilseed rape'.

(d) **Method for detection**

— Event-specific real-time PCR based method for the quantification of MON-ØØØ73-7 oilseed rape.

— Validated on genomic DNA, extracted from seeds by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx

— Reference Material: AOCS 0304-A and AOCS 0304-B are accessible via the American Oil Chemists Society at http://www.aocs.org/tech/crm

(e) **Unique identifier**

MON-ØØØ73-7

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity**

Biosafety Clearing-House (*to be entered in the Community register of genetically modified food and feed when notified*).

(g) **Conditions or restrictions on the placing on the market, use or handling of the products**

Not required.

(h) **Monitoring plan**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC (*to be entered in the Community register of genetically modified food and feed when notified*).

(i) **Post-market monitoring requirements for the use of the food for human consumption**

Not required.

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